Curetis Expects Near-Term U.S. FDA Decision on 510(k) Clearance of Unyvero LRT for BAL Specimens

- ***All formal FDA requests for additional information answered***
- ***Interactive review ongoing as review nears completion***

Amsterdam, the Netherlands, Holzgerlingen, Germany, and San Diego, CA, USA, November 25, 2019, 08:00 am CET -- Curetis N.V. (the "**Company**" and, together with its subsidiaries, "**Curetis**"), a developer of next-level molecular diagnostic solutions, today announced that the Company has filed its formal response to the FDA's AI (Additional Information request letter regarding the Company's filing for 510(k) clearance of the Unyvero LRT – Lower Respiratory Tract Application Cartridge for bronchoalveolar lavage (BAL) samples. The formal response addressed all additional information requested by FDA regarding the original submission filed on July 23, 2019. The Company now expects a near-term clearance decision.

Pneumonia patients are often treated empirically with broad spectrum antibiotic therapy. The Unyvero LRT Application Cartridge provides laboratorians and clinicians a powerful diagnostic tool to identify pathogens in lower respiratory tract infections quickly and reliably, and supports stewardship efforts to avoid unnecessary antibiotics.

In April 2018, Unyvero LRT was cleared by the U.S. FDA for tracheal aspirates for the diagnosis of lower respiratory tract infections such as pneumonia. To also offer a solution for the testing of BAL samples, Curetis in July 2019 filed for 510(k) clearance of a Unyvero LRT Application Cartridge optimized for use with BAL specimens, Unyvero LRT BAL. Together, tracheal aspirates and BAL samples are the most common specimen types used in the diagnosis of these infections. It is estimated that BAL specimens account for half of the samples obtained for the diagnosis of lower respiratory tract infections. The comprehensive LRT BAL panel covers the most clinically relevant microbial and fungal pathogens and antibiotic resistances in this indication area.

The 510(k) submission was based on clinical data from a cohort of patient samples collected at nine sites during the Company's U.S. FDA LRT trial. Further, a cohort of additional retrospective samples known to be positive for one or more pathogens was tested with Unyvero LRT BAL. Using these cohorts, the study compared the performance of the Unyvero LRT BAL Application Cartridge in detecting respiratory pathogens to the current diagnostic standard of care, i.e. microbiology culture. The trial also compared Unyvero results to a composite comparator of microbiology and independent PCR tests plus DNA sequencing. In total, the study included more than 1,400 patient samples from the combined prospective and retrospective cohorts and demonstrated an overall weighted average sensitivity of 90.1% and 94.7% and an overall average weighted specificity of 98.4% and 97.9% across all pathogens in the prospective and retrospective cohorts, respectively. The Unyvero LRT BAL Cartridge delivers comprehensive, accurate, and fast testing for lower respiratory tract infections in under 5 hours, with only a few minutes of hands-on time, whereas the standard-of-care based

on microbiology culture methods often required several days to complete microorganism identification and antibiotic susceptibility testing of a patient sample.

The study was complemented by an additional set of 240 contrived samples, which successfully confirmed performance of LRT BAL with negative patient samples that were spiked with rare pathogens and resistance markers at known concentrations. All in all, more than 5,500 LRT BAL cartridges were run as part of the comprehensive analytical and clinical performance evaluation.

“With the response to the additional information request letter filed last Friday, we expect that FDA’s review of our submission is nearing completion,” said Johannes Bacher, COO of Curetis, “and we are expecting a final clearance decision in the near term. We believe that clearance of the Unyvero LRT BAL Application Cartridge for this additional sample type will increase the total addressable market for Unyvero in the U.S., substantially giving us more opportunities to place Unyvero instruments for rapid testing of patients with suspected lower respiratory tract infections.”

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About Curetis

Curetis N.V.’s (Euronext: CURE) goal is to become a leading provider of innovative solutions for molecular microbiology diagnostics designed to address the global challenge of detecting severe infectious diseases and identifying antibiotic resistances in hospitalized patients.

Curetis’ Unyvero System is a versatile, fast and highly automated molecular diagnostic platform for easy-to-use, cartridge-based solutions for the comprehensive and rapid detection of pathogens and antimicrobial resistance markers in a range of severe infectious disease indications. Results are available within hours, a process that can take days or even weeks if performed with standard diagnostic procedures, thereby facilitating improved patient outcomes, stringent antibiotic stewardship and health-economic benefits. Unyvero in vitro diagnostic (IVD) products are marketed in Europe, the Middle East, Asia and the U.S.

Curetis’ wholly-owned subsidiary Ares Genetics GmbH offers next-generation solutions for infectious disease diagnostics and therapeutics. The ARES Technology Platform combines what the Company believes to be the most comprehensive database worldwide on the genetics of antimicrobial resistances, ARESdb, with advanced bioinformatics and artificial intelligence.

For further information, please visit www.curetis.com and www.ares-genetics.com.

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This press release includes statements that are, or may be deemed to be, “forward-looking statements.” These forward-looking statements can be identified by the use of forward-looking terminology, including the terms “believes,” “estimates,” “anticipates,” “expects,” “intends,” “targets,” “may,” “will,” or “should” and include statements Curetis makes concerning the intended results of its strategy. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. Curetis’ actual results may differ materially from those predicted by the forward-looking statements. Curetis undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.

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